IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:16-CV-313-D

THE TRANSENTERIX INVESTOR GROUP, Individually and on behalf of All Others Similarly Situated, Plaintiffs,	)	
v.	)	**ORDER**
TRANSENTERIX, INC., et al., Defendants.	)	

On June 2, 2016, plaintiff TransEnterix Investor Group, individually and on behalf of others similarly situated (collectively, "plaintiffs"), sued TransEnterix, Inc. ("TransEnterix"), two of its officers, several of its directors, and the underwriter of one of TransEnterix's securities offerings (collectively, "defendants") for violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 [D.E. 1]. On September 26, 2016, plaintiffs amended the complaint [D.E. 62]. On November 8, 2016, defendants moved to dismiss the amended complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure [D.E. 82, 84] and filed memoranda in support [D.E. 83, 85]. On December 22, 2016, plaintiffs responded in opposition [D.E. 88]. On January 20, 2017, defendants replied [D.E. 92, 93]. As explained below, the court grants the motions to dismiss.

I.

TransEnterix is a medical-device company that manufactures robotics for use in surgeries. Am. Compl. [D.E. 62] ¶ 3. Among TransEnterix's products was the robotically enhanced surgical device known as the SurgiBot system ("SurgiBot"). Id. With a price tag of $500,000, SurgiBot was designed as a lower-cost alternative for the surgical-robot industry. Id.

On June 1, 2015, TransEnterix submitted a "510(k) application" for SurgiBot to the Food and Drug Administration ("FDA"). Id. ¶¶ 4, 7. Otherwise known as a "premarket notification," a 510(k) application gives the FDA 90 days' notice of a manufacturer's intent to market a medical device. Id. ¶ 5. During the intervening 90 days, the FDA determines whether the device is "substantially equivalent" to a device already on the market. Id. Until the FDA makes that determination, a manufacturer cannot market the device. Id. ¶ 6.

On July 27, 2015, the FDA hosted a public forum designated "Robotically-Assisted Surgical Devices: Challenges and Opportunities." Id. ¶ 28(a). At the forum, speakers—including the FDA's Director of the Office of Device Evaluation and Deputy Director of the Division of Surgical Devices—signaled an increased scrutiny of robotically assisted devices like SurgiBot. Id. ¶ 28(a)–(g). For example, the FDA expected applications to include "human-factors data," i.e., the application of knowledge about medical-device users' abilities, limitations, and other characteristics to the design of medical devices. Id. ¶ 28(d), (h).

In August 2015, the FDA requested additional information from TransEnterix. Id. ¶¶ 28(k), 53. "Among other things, the FDA's request . . . focused on human factors testing and evaluation." Id. ¶ 28(l). TransEnterix "immediately undertook the actions necessary to respond to [the] request." Id. ¶ 72. In February 2016, TransEnterix finalized its response, "attempt[ing] to satisfy the FDA's requests concerning human factors issues." Id. ¶ 28(k)–(l). "In total, over the course of the submission [TransEnterix] provided over 11,000 pages of requested material to the FDA." Id. ¶ 72.

In February 2016, the FDA issued several guidance documents. Id. ¶ 28(h). The guidance expressed the FDA's expectation that manufacturers of robotic surgery devices would support their 510(k) applications with human-factors data. Id. The guidance recommended that manufacturers "either provide the data and testing identified within the guidance documents or provide a detailed

explanation as to why such data is not necessary." Id.

On February 9, 2016, TransEnterix commenced an "at-the-market" stock offering. Id. ¶¶ 2, 31, 71, 97, 118. TransEnterix detailed the offering in a supplemental prospectus (the "2016 ATM Prospectus") concerning the company's Form S-3 Registration Statement initially filed with the SEC on January 8, 2014. See id. ¶¶ 101, 104. The 2016 ATM Prospectus stated, in relevant part, that:

> On June 1, 2015, we submitted our 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. In August 2015, the FDA requested additional information related to the SurgiBot System 510(k) submission. We responded to that additional information request in February 2016. *We anticipate that we will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016 and thereafter intend to launch sales of the SurgiBot System during the second quarter of 2016.*

Id. ¶ 104 (emphasis in original). The 2016 at-the-market offering involved the sale of approximately 8.7 million shares. Id. ¶¶ 31, 119. Plaintiffs purchased common stock "in connection with" the 2016 at-the-market offering. Id. ¶ 118.

The day after TransEnterix commenced the at-the-market offering, TransEnterix announced via a press release that it had completed its response to the FDA's request for additional information and discussed plans for SurgiBot:

> Since September 30, 2015, the Company has raised $18 million in net proceeds at an average price of $3.23 per share under its $25 million "at-the-market" (ATM) equity sales facility that was established in February 2015. There is no further availability under this facility. *The proceeds from these sales will be utilized to continue to support investments for the commercialization of* the ALF-X® system in Europe, as *well as the SurgiBot in the United States, following FDA clearance.*
>
> * * *
>
> We are pleased to have completed our response to the FDA and strengthened our balance sheet. *We continue to expect FDA clearance for the SurgiBot System in the first quarter of this year, and our cash position allows us to accelerate our transition to commercializing both the ALF-X and the SurgiBot.*

Id. ¶ 44 (emphasis in original).

On March 3, 2016, TransEnterix issued a press release expressing optimism for SurgiBot's FDA approval prospects and the company's intentions to commercialize SurgiBot once approved:

> 2015 was a transformative year for TransEnterix, as we are now positioned as a global surgical robotics company. *In 2016, our focus will shift from product development to commercial execution,*" said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We will continue building the infrastructure to support the commercialization of the ALF-X in multiple countries that accept CE Mark, *and we remain focused on achieving FDA clearance for the SurgiBot by the end of March, 2016, and preparing for a U.S. commercial launch.*"
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> * * *
>
> During 2016, the Company will continue to expand its sales and service infrastructure for the ALF-X System in Europe and the Middle East. *Following SurgiBot FDA clearance, the Company intends to expand its U.S. sales and service infrastructure, develop training sites and work with key opinion leaders to gain clinical experience on SurgiBot.* The Company plans to submit a 510(K) application to the FDA for the ALF-X system in the fourth quarter of 2016 and capitalize on the U.S. market opportunity in 2017 with a dual-platform portfolio.

Id. ¶¶ 47–48 (emphasis in original).

In a conference call that same day, two of TransEnterix's officers echoed the press release. TransEnterix's President and CEO Todd Pope ("Pope") said:

> In the second quarter of 2015, we filed our 510(k) which was a big undertaking. It was a very extensive and comprehensive filing. We felt very good about it. As planned, we knew we'd hear back from the FDA with some of their feedback and questions, which we did in the Q3. *And we've been taking the last quarter or two to really build up our answers to their questions. We've had a very proactive relationship with the FDA, very good. It continues to this day. And in the first quarter of 2016, we finalized our response and sent it back to the FDA.*
>
> We built eight complete systems of the SurgiBot and over 1,200 instruments in support of this machine. *So we really felt like we got good experience with our manufacturing. We continue to expect about Q1 FDA clearance, which would be later this month.* I just have to say, as I step back and look at 2015; it was a tremendous year for the company. We really hit all of our targets that we set out to and then we took on a new one with the acquisition of ALF-X and that's turned out to be tremendous. So we're really proud of 2015 and super excited as we turn the page to look toward 2016.

* * *

With the SurgiBot, following clearance, which we expect later this month, we want to expand our U.S. sales and service infrastructure. We want to early on develop trainee sites and work with those sites to develop key opinion leaders and gain valuable clinical experience as you do any time you launch a new platform.

* * *

[W]ith SurgiBot following our FDA clearance, our plans are as follows. We want to hire three area sales managers shortly after clearance. As we've been talking to you, we've been interviewing for a while. We've got a tremendous pipeline of candidates and we've got them lined up to be able to make those hires. And we want to go out and establish our commercial foundation. It always involves developing early clinical experience, making sure that the sites you sell into are willing to host other accounts and be a training site, you want to get a KOL or key opinion leader network, so they can go out and not only have a podium presence but a publication presence. And then we want to build a customer support infrastructure with service and the other things that go around early commercialization.

Id. ¶ 50 (emphasis and alteration in original). When asked about another of TransEnterix's devices—the ALF-X system—Pope responded that the company had yet to meet with the FDA concerning the ALF-X and wanted to "finalize [its] work with SurgiBot with [the FDA] and then turn [its] attention to" the ALF-X. Id. ¶ 51. When asked for insight into TransEnterix's last interaction with the FDA, Pope stated that:

> As we've characterized in the past, we filed, [the FDA] gave us their questions in a timely manner as we expected, we responded to their questions in a timely manner as they expected. And they confirmed that they received our questions and they're working through them. *We have a good interaction with them. Any interaction over the prior month or a couple of weeks have just been clarifying questions. So everything continues to be on the path that we set out last year.*

Id. ¶ 52 (emphasis and alteration in original).

On March 3, 2016, TransEnterix also filed with the SEC its 2015 annual report on Form 10-K (the "2015 Form 10-K"). Id. ¶ 53. In relevant part, 2015 Form 10-K stated:

> In August 2015, the FDA requested additional information related to the SurgiBot System 501(k) submission. The Company responded to the additional information request in February 2016. *The Company anticipates that it will receive FDA*

clearance for the SurgiBot System by the end of the first quarter of 2016, and thereafter intends to launch sales of the SurgiBot System during the second quarter of 2016.

Id. (emphasis in original).

On March 9, 2016, the price of TransEnterix stock closed at $4.36/share, up from $3.20/share on March 3, 2016, the day of TransEnterix's press release and conference call. Id. ¶ 56.

On March 11, 2016, TransEnterix filed prospectuses concerning the sale of shares of TransEnterix common stock to certain individuals or entities. Id. ¶ 57. Both prospectuses stated:

> On June 1, 2015, we submitted our 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. In August 2015, the FDA requested additional information related to the SurgiBot System 510(k) submission. We responded to that additional information request in February 2016. *We anticipate that we will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016 and thereafter intend to launch sales of the SurgiBot System during the second quarter of 2016.*

Id. ¶ 58 (emphasis in original).

On March 24, 2016, TransEnterix issued an update on SurgiBot's 501(k) application. Id. ¶ 61. The press release stated that TransEnterix had received a status update from the FDA, which

> advised the Company that it has not yet concluded the review of the Company's 510(k) submission and provided an update on the status of the filing. The Company has updated its timing expectations and now expects to receive a decision from the FDA by mid-April, 2016. The Company previously expected a decision from the FDA in the first quarter of 2016.
>
> *"We have been engaged in constructive dialogue with the FDA throughout the entire submission process," said Todd M. Pope, President and Chief Executive Officer of TransEnterix. "We appreciate the proactive exchange with the FDA and look forward to their decision, and continue to expect clearance for the SurgiBot."*

Id. ¶ 61 (emphasis in original).

After the market closed on April 20, 2016, TransEnterix revealed that the previous day the FDA had notified the company that SurgiBot "does not meet the criteria for substantial equivalence."

Id. ¶ 9; see id. ¶ 65. "[O]n abnormally high trading volume of more than 21.5 million shares," the price of TransEnterix stock dropped dramatically. Id. ¶ 12, see id. ¶ 68. After closing at $4.74/share on April 20, 2016, the stock opened at $1.57/share the next morning. Id. ¶¶ 12, 68. The stock price fluctuated throughout the day, ultimately closing at $2.27/share—a more than 50% drop. Id.

On May 10, 2016, TransEnterix announced that it no longer intended to seek FDA approval of SurgiBot. Id. ¶¶ 10–11, 69–70. Instead, TransEnterix planned to submit a 501(k) application for the ALF-X in the fourth quarter of 2016. Id. ¶¶ 10, 69–70. During a conference call held that day after the market closed, Joseph P. Slattery ("Slattery"), TransEnterix's Executive Vice President and CFO, told listeners that TransEnterix would reduce investment in SurgiBot production and development. Id. ¶ 11. Pope echoed these plans and stated that the FDA's reason for its denial "included items that [TransEnterix] believe[d] [it] had adequately addressed" in its response to the FDA. Id. ¶ 72. Pope also opined that the "landscape [had] changed" for robotic devices during the 510(k) process as a result of the FDA's "public forum" and "three or four guidance documents" released during SurgiBot's application process. Id. ¶ 73.

The price of TransEnterix stock fell again. "[O]n elevated trading volume of more than 5.5 million shares," the stock price fell from $2.06/share on May 10, 2016, to $1.84/share at the market's close on May 11, 2016. Id. ¶¶ 12, 76.

On June 2, 2016, plaintiff TransEnterix Investor Group sued TransEnterix, Pope, Slattery, several of TransEnterix's directors, and Cantor Fitzgerald & Co., the underwriter for the 2016 at-the-market offering [D.E. 1]. TransEnterix Investor Group consists of lead plaintiffs representing two classes of investors who acquired stock in TransEnterix. Am. Compl. ¶¶ 1–2. The first group includes all persons who purchased or otherwise acquired TransEnterix stock between February 10, 2016, and May 10, 2016 (the "Exchange Act Class Period"). Id. ¶ 1. The second group includes a

subclass of investors who purchased or otherwise acquired TransEnterix stock through the company's "at-the-market" offering between February 9, 2016, and April 19, 2016 (the "Securities Act Class Period"). Id. ¶ 2.

Plaintiffs' claims arise under both the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act"). Essentially, plaintiffs contend that the statements emphasized above omitted material facts necessary to make the statements not misleading. TransEnterix allegedly used the misleading statements to deceive the public about TransEnterix's prospects and to artificially inflate its stock price. According to plaintiffs, the statements express TransEnterix's optimism that the FDA would approve SurgiBot's 510(k) application and TransEnterix's intention, following FDA approval, to commercialize SurgiBot. Plaintiffs contend that the emphasized statements were misleading because TransEnterix omitted a material fact: TransEnterix had not provided human-factors data, and as a result, FDA approval was unlikely.

II.

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) for "failure to state a claim upon which relief can be granted" tests whether the complaint is legally and factually sufficient. See Fed. R. Civ. P. 12(b)(6); Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007); Coleman v. Md. Court of Appeals, 626 F.3d 187, 190 (4th Cir. 2010), aff'd, 566 U.S. 30 (2012); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008); accord Erickson v. Pardus, 551 U.S. 89, 93–94 (2007) (per curiam). A court need not accept a complaint's "legal conclusions, elements of a cause of action, and bare assertions devoid of further factual enhancement." Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009). The court, however, "accepts all well-pled facts as true and construes these facts in the

light most favorable to the plaintiff in weighing the legal sufficiency of the complaint." Id. Construing the facts in this manner, a complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Id. (quotation omitted).

III.

Plaintiffs allege that TransEnterix and the TransEnterix defendants violated Sections 10(b), 20(a), and 20A of the Securities Exchange Act as well as SEC Rule 10b-5. In support, plaintiffs rely on statements made in TransEnterix's February 10th, March 3rd, and March 24th, 2016 press releases, March 3, 2016 conference call, 2015 Form 10-K annual report, and prospectuses filed on March 11, 2016.

A.

Section 10(b) of the Securities Exchange Act forbids the "use or employ, in connection with the purchase or sale of any security . . . , [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b–5 implements section 10(b) by declaring it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 CFR § 240.10b–5. To succeed on a Section 10(b) or Rule 10b-5 claim, a plaintiff must prove six elements: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security;

(4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, 552 U.S. 148, 157 (2008). Defendants argue that plaintiffs fail to adequately allege a material omission, scienter, and loss causation.

1.

The Private Securities Litigation Reform Act of 1995 ("PSLRA") "imposes a heightened pleading standard on fraud allegations in private securities complaints" Yates v. Mun. Mortg. & Equity, LLC, 744 F.3d 874, 885 (4th Cir. 2014). Under the PSLRA, plaintiffs must make specific allegations of false or misleading statements or else face dismissal. See 15 U.S.C. 78u-4(b)(1); Cozzarelli v. Inspire Pharm. Inc., 549 F.3d 618, 623 (4th Cir. 2008). A complaint must include "each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). Where a plaintiff alleges that a defendant's statements omitted material information, the plaintiff must identify an omitted fact and identify how omitting that fact rendered the statements misleading. See Ottmann v. Hanger Orthopedic Grp., Inc., 353 F.3d 338, 342–43 (4th Cir. 2003); Longman v. Food Lion, Inc., 197 F.3d 675, 682 (4th Cir. 1999). The plaintiff must plead these elements with specificity. See Cozzarelli, 549 F.3d at 625; Teachers' Ret. Sys. of La. v. Hunter, 477 F.3d 162, 172–75 (4th Cir. 2007); Nolte v. Capital One Fin. Corp., 390 F.3d 311, 315–17 (4th Cir. 2004).

Initially, the parties debate the import of the Supreme Court's decision in Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund, 135 S. Ct. 1318 (2015). There, the Court analyzed Section 11 of the Securities Act, which allows purchasers of a security to sue if any part of a registration statement "contained an untrue statement of a material fact or omitted to state a

material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). The Court considered how these phrases applied to statements of opinion. To hold an issuer liable under the omissions clause for an opinion, the Court held that:

> The investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.

Omnicare, Inc., 135 S. Ct. at 1332. "The core inquiry is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" Tongue v. Sanofi, 816 F.3d 199, 210–14 (2d Cir. 2016) (quoting Omnicare, 135 S. Ct. at 1329).

Defendants contend that the challenged statements are statements of opinion subject to Omnicare. See [D.E. 85] 22–23 & n.16–17. Plaintiffs disagree. See [D.E. 88] 19. The Fourth Circuit has not addressed whether Omnicare applies to claims brought under the Securities Exchange Act or discussed what type of statements qualify as opinions subject to Omnicare. Given the nature of plaintiffs' claim, the court need not grapple with these issues. Whether Omnicare applies or not, plaintiffs fail to adequately allege a material omission.

At bottom, plaintiffs allege (though not in the complaint) that defendants' optimistic statements of anticipated FDA approval and intent to commercialize SurgiBot once approved were misleading because the statements omitted that SurgiBot's 510(k) application lacked human-factors data. See [D.E. 88] 16–17. Phrased in terms of Omnicare, these allegations concern facts going to the basis of the issuer's opinion—the knowledge TransEnterix had—whose omission made the optimistic statements misleading. If Omnicare does apply, plaintiffs' allegations do not satisfy its dictates. See Tongue, 816 F.3d at 210–14. Plaintiffs have not identified any material facts underlying defendants' statements of opinion that conflicted with what a reasonable investor would

infer from those statements. If Omnicare does not apply, the outcome is the same. Plaintiffs have not adequately alleged the existence of facts the omission of which made the statements materially misleading. Thus, whether or not Omincare applies, plaintiffs' claim fails.

In their response to defendants' motion to dismiss, plaintiffs summarize their claim as follows: The FDA told TransEnterix that human-factors data was necessary for SurgiBot's 510(k) application, but TransEnterix did not provide human-factors data. As a result, SurgiBot's approval was unlikely, and TransEnterix's statements concerning FDA clearance and TransEnterix's commitment to commercializing SurgiBot were misleading. See [D.E. 88] 7, 16–17, 27.

The amended complaint's allegations do not support this theory. The amended complaint alleges that the FDA's public forum and guidance expressed the FDA's expectation that 510(k) applications for products like SurgiBot would contain human-factors data. See Am. Compl. ¶ 28(a)–(i). During SurgiBot's review process, the FDA communicated with TransEnterix in a manner consistent with the FDA's public statements and guidance. Id. ¶ 28(m). The FDA's request for additional information in August 2015 "focused on human factors testing and evaluation," and the TransEnterix defendants "attempted to satisfy the FDA's requests concerning human-factors issues." Id. ¶ 28(l). The FDA ultimately denied SurgiBot's 510(k) application because it "was insufficient for 'substantial equivalence' findings." Id. ¶ 28(o). These allegations do not support an inference that SurgiBot's 510(k) application lacked human-factors data and thus was unlikely to win approval.

Although the FDA asked TransEnterix for "additional information focused on human factors testing and evaluation," TransEnterix "attempted to satisfy" the FDA's request. "In total, over the course of the submission [TransEnterix] provided over 11,000 pages of requested material to the FDA." Am. Compl. ¶ 72. The amended complaint does not allege that TransEnterix's response did not supply adequate human-factors data, or that the FDA's communications with TransEnterix

included discussions concerning a perceived inadequacy of human-factors data. Nor does the amended complaint allege that the FDA declined to approve SurgiBot for lack of human-factors data. Instead, the amended complaint says the FDA concluded that the application was "insufficient for 'substantial equivalence' findings." Plaintiffs do not claim that this determination turns solely on the existence or not of sufficient human-factors data. In short, the amended complaint's allegations do not warrant the inference plaintiffs draw. Plaintiffs have alleged no specific facts to support their assertion that approval of SurgiBot's 510(k) application was "substantially unlikely" in light of the fact TransEnterix had not provided human factors data. See, e.g., Johnson v. Pozen Inc., No. 1:07-CV-599, 2009 WL 426235, at *20 (M.D.N.C. Feb. 19, 2009) (unpublished).

In opposition to this conclusion, plaintiffs discuss numerous, distinguishable cases. In each of those cases, the plaintiffs did what plaintiffs here failed to do: include specific allegations in the complaint identifying a specific fact or facts whose omission made the challenged statements misleading. For example, in In re Nuvelo, Inc., 668 F. Supp 2d 1217 (N.D. Cal. 2009), the plaintiff alleged that for the company's drug to gain approval, the FDA required a "statistically significant difference" between the drug and a placebo. Id. at 1221. The company issued a press release likening its planned clinical trial with one that had already met the FDA's standard. Id. The statement implied a likelihood that the company's drug, like that in the comparative study, would win FDA approval. But the plaintiffs alleged in the complaint that the company failed to divulge that it and the FDA had agreed the drug's approval depended on the trial "achieving a much higher threshold for statistical significance" than the comparative trial had to meet. Id. Thus, the plaintiffs alleged in their complaint the existence of a fact—the agreement for a higher statistical threshold—that rendered the company's statements misleading. The other cases relied upon by plaintiffs exhibited a similar level of particularized allegations of omitted facts that were at odds with

the defendants' optimistic public statements. See [D.E. 88] 12 n.3.

The amended complaint does not contain these types of particularized allegations. Instead, finding the requisite fact whose omission made the challenged statements misleading depends on drawing inferences the amended complaint's allegations do not warrant. As a result, plaintiffs fail to adequately allege that the challenged statements were misleading in light of omitted facts.

2.

Alternatively, plaintiffs have not adequately alleged that defendants acted with the requisite mental culpability. A private securities complaint alleging that the defendant made false or misleading statement must, "with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). That requisite state of mind is scienter. "To establish scienter, a plaintiff must prove that the defendant acted with 'a mental state embracing intent to deceive, manipulate, or defraud.'" Yates, 744 F.3d at 884 (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007)). "At the pleading stage, alleging either intentional or severely reckless conduct is sufficient." Id. Severe recklessness exists when "the danger of misleading investors was either known to the defendant or so obvious that the defendant must have been aware of it." Cozzarelli, 549 F.3d at 623; see Yates, 744 F.3d at 884.

As for the "strong inference" standard, "[i]t does not suffice that a reasonable factfinder plausibly could infer from the complaint's allegations the requisite state of mind." Tellabs, Inc., 551 U.S. at 314. Instead, "an inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id.; see Yates, 744 F.3d at 885. The court must determine "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation,

scrutinized in isolation, meets that standard." Tellabs, Inc., 551 U.S. at 323. "Omissions and ambiguities count against an inference of scienter because a complaint's factual allegations must be stated with particularity." Yates, 744 F.3d at 885 (alteration and quotation omitted). If the court "find[s] the inference that defendants acted innocently, or even negligently, more compelling than the inference that they acted with the requisite scienter," the court must dismiss the complaint. Id.; see Cozzarelli, 549 F.3d at 624.

Plaintiffs rely on four allegations concerning scienter: TransEnterix knew that the SurgiBot's 510(k) application lacked human-factors data and that, absent such data, "approval for the SurgiBot was incredibly unlikely," [D.E. 88] 22; TransEnterix started investing more resources in the ALF-X, Am. Compl. ¶¶ 28(p)–(t); TransEnterix engaged in revenue-raising operations, id. ¶¶ 30–34; and defendants Pope and Slattery purchased TransEnterix stock several days after TransEnterix announced its intentions to shift its attention to the ALF-X following the SurgiBot's failure to achieve FDA clearance. Id. ¶¶ 35–36.

As shown by the lack of citation to the amended complaint supporting it, plaintiffs' first allegation has no basis in the pleadings. Thus, the court rejects it.

According to plaintiffs, the allegations concerning the ALF-X and TransEnterix's revenue-raising operations combine to demonstrate a motive for TransEnterix to mislead investors. That motive comes in the form of obtaining financing for the ALF-X. TransEnterix purchased the ALF-X in September 2015. Am. Compl. ¶ 28(q). TransEnterix estimated that it could not submit a 510(k) application for the ALF-X until late 2016. Id. ¶ 30. But TransEnterix's cash reserves could not last that long. Id. Thus, TransEnterix commenced an at-the-market offering to raise capital. Id. ¶ 31. According to plaintiffs, by initiating the offering during the class period, TransEnterix could take advantage of the inflated stock price plaintiffs attribute to TransEnterix's optimistic statements about

SurgiBot. Id. ¶¶ 31, 33. Had TransEnterix commenced the offering after the FDA denied SurgiBot's 510(k) application, TransEnterix would not have raised enough capital to see the ALF-X through to profitability. Id. ¶ 33.

Defendants respond that TransEnterix made public its intentions to invest in the ALF-X and strive to commercialize it. See, e.g., [D.E. 86-4] 6–12 (Mar. 3, 2016 conference call); [D.E. 86-7] 6 (Feb. 10, 2016 press release); [D.E. 86-8] 6 (Mar. 3, 2016 press release). Rather than suggest that TransEnterix was aware of SurgiBot's impending disapproval, TransEnterix's investment and development of the ALF-X confirms that the company "was acting on its disclosed, near-term priorities of focusing on both the SurgiBot (in the U.S.) and the ALF-X (outside the U.S.)." [D.E. 85] 33.

Plaintiffs acknowledge that "[t]he ALF-X was far and away the Company's most viable product considering the fact that it already had received a 'CE Mark' (European marketing approval), undergone significant clinical testing, and was supported by a developed sales infrastructure team." [D.E. 88] 22–23; see Am. Compl. ¶ 28(q). The ALF-X had already proven its worth in several European hospitals. Am. Compl. ¶ 28(q). With this background, the warning sign plaintiffs construct from TransEnterix's financing run lends itself to a more compelling, benign interpretation: TransEnterix focused on the ALF-X and sought to raise money because of its potential upside.

This inference of non-malicious reasons for TransEnterix's 2016 at-the-market offering becomes more cogent given that plaintiffs do not allege that TransEnterix could use the offering's returns only to finance the ALF-X. TransEnterix commenced the offering the month after it completed its response to the FDA's request for additional information to supplement SurgiBot's 510(k) application. Thus, commencing the offering just as well suggests TransEnterix's optimism for SurgiBot's approval. Under this view, TransEnterix opened the offering when it did to raise

money for the anticipated push to commercialize SurgiBot and for the AFL-X. This benign inference for the at-the-market offering is more compelling than the one plaintiffs suggest. "Indeed, the motivation[] to raise capital" is "common to every company and thus add[s] little to an inference of fraud." Cozzarelli, 549 F.3d at 627; see Yates, 744 F.3d at 891. This benign inference applies even if SurgiBot was riskier than the AFL-X. After all, "a strong inference of fraud does not arise merely from seeking capital to support a risky venture." Cozzarelli, 549 F.3d at 627; see Ash v. PowerSecure Int'l, Inc., No. 4:14-CV-92-D, 2015 WL 5444741, at *13 (E.D.N.C. Sept. 15, 2015) (unpublished).

Plaintiffs' final scienter allegation involves allegedly opportunistic stock purchases by Slattery and Pope. "Insider trading allegations will only support an inference of scienter if the timing and amount of a defendant's trading were unusual or suspicious." Yates, 744 F.3d at 890 (quotation omitted). Relevant factors include "the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved." Id. (quotation omitted).

On May 10, 2016—roughly 20 days after the FDA rejected SurgiBot's 510(k) application—TransEnterix announced it would shift focus to the ALF-X and delay any re-filing for SurgiBot until after the ALF-X obtained clearance. Am. Compl. ¶ 70. On May 13, 2016, Slattery purchased 50,000 shares of TransEnterix stock for $95,850. Id. ¶ 35. Had Slattery purchased the shares in the two weeks before the FDA's April 20, 2016 decision rejecting the SurgiBot, he would have spent roughly $500,000 for 50,000 shares. Id. Slattery owned zero shares before his purchase. Id.

As for Pope, on May 16, 2016, he exercised stock options for 150,000 shares of TransEnterix stock worth $288,000. Id. ¶ 36. Had Pope exercised the options in the two weeks before the FDA's rejection of SurgiBot the same shares would been worth $750,000. Id. By exercising the options

when he did, Pope secured favorable tax consequences. Id. Pope owned 21,010 shares before this transaction. Id.

The inference plaintiffs apparently draw from these purchases does not track the typical insider-transaction claim. Plaintiffs usually focus on an insider who sells stock during the class period before the release of "bad" news and while the stock price is allegedly inflated. See Yates, 744 F.3d at 890–91; Cozzarelli, 549 F.3d at 627–28; In re PEC Sols., Inc. Sec. Litig., 418 F.3d 379, 390 (4th Cir. 2005). An inference of scienter from such transactions is straightforward: an insider who sells stock during the class period before the release of "bad" news has a motive to reap the benefits of selling stock with an inflated price. See In re PEC Sols., Inc., 418 F.3d at 390.

Plaintiffs rely on a different inference. According to plaintiffs, by waiting to purchase the stock or to exercise the options until after the negative disclosures concerning Surgibot, Pope and Slattery saved themselves tens of thousands of dollars. This timing supposedly shows "that Slattery and Pope knew they would be releasing negative corporate news and decided to take advantage of it when TransEnterix's stock price declined." [D.E. 88] 24. Plaintiffs do not cite any cases inferring scienter from such post-class period stock purchases. In any event, the inference supplied by plaintiffs' theory concerning these transactions is, at best, slight.

Plaintiffs also rely on Zak v. Chelsea Therapeutics International, Ltd., 780 F.3d 597 (4th Cir. 2015). There, the plaintiffs alleged that: (1) the FDA explicitly told the company the agency expected two successful efficacy studies before approving a new drug application; (2) only one of the company's several studies met its efficacy goal, but that goal was a revised one that did not involve sufficiently long treatment periods; (3) the FDA again warned the company "that a single successful study typically was not sufficient to support approval of a new drug"; (4) the company nonetheless submitted the new drug application and issued optimistic statements about the

company's interactions with the FDA and the drug's chances of approval; (5) the FDA gave the company a briefing document in which the FDA recommended not approving the drug; (6) the company issued a press release that omitted the FDA's recommendation; and (7) the FDA ultimately denied the new drug application because the FDA required an additional successful study demonstrating the drug's efficacy. Id. at 601–04. The Fourth Circuit concluded that these allegations created a strong inference of scienter. "Critically," the court said, the plaintiffs alleged that the company knew the FDA expected two successful efficacy studies and was aware that the data submitted fell short. Id. at 609. The plaintiffs pleaded facts demonstrating that the defendants knew of the problems and knowingly or recklessly misled investors "by failing to disclose critical information received from the FDA during the new drug application process." Id. at 610.

Plaintiffs' allegations do not parallel those in Zak. Plaintiffs allegations instead mirror those in Yates, in that the facts support a more compelling inference that the TransEnterix defendants "were, at most, negligent." Yates, 744 F.3d at 893; see id. at 885–94. Assuming that SurgiBot's 510(k) application lacked sufficient human-factor's data, the more compelling inference drawn from the facts is that defendants simply misjudged the adequacy of the filing. TransEnterix took six months to reply to the FDA's request for additional information, and its reply (which ultimately included over 11,000 pages) specifically addressed human-factors data. TransEnterix could well have thought it adequately responded to the FDA's request for information. Moreover, Pope expressed that opinion in the May 10, 2016 conference call. As Pope said, "[t]he reason stated by the FDA for this decision included items that we believe we had adequately addressed through the interactive period." Am. Compl. ¶ 72. Back and forth dialogue with the FDA characterizes the application process, and "inherent in the nature of a dialogue are differing views." Tongue, 816 F.3d at 211. "That the [TransEnterix] defendants were ultimately wrong is not enough to support an

inference of scienter." Yates, 744 F.3d at 887.[1]

B.

Section 20(a) of the Exchange Act "assigns joint and several liability to a person who controls another who violates a securities regulation." Hunter, 477 F.3d at 168. Section 20A "provides a private right of action against one who engaged in insider trading." Id. at 188. Claims under Sections 20(a) and 20A are derivative of claims under Section 10(b) and Rule 10b-5. See Cozzarelli, 549 F.3d at 628; Hunter, 477 F.3d at 168. Thus, plaintiffs' failure to adequately allege a violation of Section 10(b) or Rule 10b-5 requires dismissal of their claims under Sections 20(a) and 20A. See Yates, 894 F.3d at 894 n.8; Cozzarelli, 549 F.3d at 628; Hunter, 477 F.3d at 188.

C.

Alternatively, several of the challenged statements are not actionable due to the PSLRA's safe harbor. The PSLRA provides a "safe harbor" for certain forward-looking statements. See 15 U.S.C. § 78u-5(c). This safe harbor precludes liability for allegedly material misrepresentations under certain circumstances, including if: (1) the forward-looking statement is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement"; (2) the forward-looking statement is "immaterial;" or (3) the plaintiff fails to prove that the forward-looking statement was made by a person—or if the statement a business entity's, was made or approved by an officer—"with actual knowledge by that person [or officer] that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1). "The safe harbor is

[1] In light of this conclusion, the court need not address defendants' argument that the amended complaint fails to adequately allege loss causation.

written in the disjunctive; that is, a defendant is not liable if the forward-looking statement is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." Slayton v. Am. Exp. Co., 604 F.3d 758, 766 (2d Cir. 2010) (emphasis in original).

Defendants assert that the PSLRA's safe harbor protects the statements expressing anticipation of FDA approval and TransEnterix's intention, following approval, to commercialize SurgiBot. Defendants omit from their safe-harbor arguments the portions of the challenged statements optimistically characterizing TransEnterix's interactions with the FDA.

All safe-harbor categories require the statements to be forward-looking. In relevant part, the PSLRA defines "forward-looking statement[s]" to include: (1) statements regarding "the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer"; and (2) "any statement of the assumptions underlying or relating to" those plans or objectives. 15 U.S.C. § 78u-5(i)(1)(B), (D).

Predictions about future product launches are forward-looking. They are plans of management for future operations. See Julianello v. K-V Pharm. Co., 791 F.3d 915, 921 (8th Cir. 2015); In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 537–38 (S.D.N.Y. 2015), aff'd sub nom. Tongue v. Sanofi, 816 F.3d 199 (2d Cir. 2016); Plymouth Cty. Ret. Ass'n v. Primo Water Corp., 966 F. Supp. 2d 525, 556–57 (M.D.N.C. 2013); Johnson, 2009 WL 426235, at *21. Moreover, as assumptions related to the company's plan for its products, "[p]rojections about the likelihood of FDA approval are forward-looking statements." Kovtun v. VIVUS, Inc., No. C 10-4957 PJH, 2012 WL 4477647, at *12 (N.D. Cal. Sept. 27, 2012) (unpublished), aff'd sub nom. Ingram v. VIVUS, Inc., 591 F. App'x 592 (9th Cir. 2015) (per curiam) (unpublished); see In re Genzyme Corp. Sec.

Litig., 754 F.3d 31, 44–45 (1st Cir. 2014); In re Sanofi, 87 F. Supp. 3d at 535; Johnson, 2009 WL 426235, at *21.

Here, the challenged statements fall within the safe harbor. The clearance statements—those regarding TransEnterix's expectations that the FDA would approve SurgiBot—were assumptions underlying TransEnterix's plans or objectives concerning SurgiBot. The commercialization statements—those regarding TransEnterix's expectation that it would commercialize SurgiBot following FDA clearance—concerned management's plans and objectives for future operations.

In opposition to this conclusion, plaintiffs argue that TransEnterix's statements are not forward-looking. In support, plaintiffs cite several cases for the proposition that "a mixed/present future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." [D.E. 88] 28 (alteration omitted). They apply this argument to TransEnterix's statements about commercializing SurgiBot, which plaintiffs claim were materially misleading "because they misrepresented [TransEnterix's] then-existing intention with regard to the device." Id. According to plaintiffs, these statements refer to the present—and are not forward-looking—because TransEnterix misrepresented its then-existing intentions regarding SurgiBot.

The Fourth Circuit has rejected attempts to color forward-looking statements as "present intentions" in a bid to alter their forward-looking nature. That statements can be "characterized as statements of present belief regarding future events" does not render them non-forward-looking. See Marsh Grp. v. Prime Retail, Inc., 46 F. App'x 140, 146–47 (4th Cir. 2002) (per curiam) (unpublished). All plans and objectives for future operations "can be characterized as presently held beliefs." Id.; see Institutional Inv'rs Grp. v. Avaya, Inc., 564 F.3d 242, 255–56 (3d Cir. 2009). Moreover, the commercialization statements are inextricably linked to a future event: FDA

clearance. See Julianello, 791 F.3d at 921. Until the FDA's clearance decision, it could not be determined whether TransEnterix indeed intended to commercialize and market SurgiBot as claimed in the commercialization statements. See id.

The clearance and commercialization statements are forward-looking and within the safe harbor. Accordingly, "these statements are not actionable if they are covered by any of the three disjunctive categories established by the PSLRA safe harbor." In re Sanofi, 87 F. Supp. 3d at 535. Defendants contend that the clearance and commercialization statements are not actionable under any of three prongs. The court need only address the third prong, which renders forward-looking statements not actionable unless they were made with actual knowledge that they were false or misleading. See 15 U.S.C. § 78u-5(c)(1)(B). As demonstrated, plaintiffs have not adequately alleged that defendants made these forward-looking statements with actual knowledge that the statements were false or misleading when made. Thus, the safe harbor protects these statements.

IV.

A.

Section 11 of the Securities Act gives purchasers of securities a right of action against an issuer and others, including underwriters, for material misstatements or omissions in registration statements. See 15 U.S.C. § 77k(a); Omnicare, Inc., 135 S. Ct. at 1323. The registration statement is actionable if it "contained an untrue statement of a material fact or omitted to state a material fact . . . necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). "Section 11 thus creates two ways to hold issuers liable for the contents of a registration statement—one focusing on what the statement says and the other on what it leaves out." Omnicare, Inc., 135 S. Ct. at 1323. The buyer need not prove that the defendant acted with scienter. Id. "If a plaintiff purchased a

security issued pursuant to a registration statement, he need only show a material misstatement or omission to establish his prima facie case." Herman & MacLean v. Huddleston, 459 U.S. 375, 382 (1983).

As the basis for their Section 11 claim, plaintiffs cite allegedly misleading statements contained in the 2016 ATM Prospectus:

> On June 1, 2015, we submitted our 510(k) application to the FDA for clearance of the SurgiBot System which was accepted for review. In August 2015, the FDA requested additional information related to the SurgiBot System 510(k) submission. We responded to that additional information request in February 2016. *We anticipate that we will receive FDA clearance for the SurgiBot System by the end of the first quarter of 2016 and thereafter intend to launch sales of the SurgiBot System during the second quarter of 2016.*

Am. Compl. ¶ 104 (emphasis in original); see [D.E. 82-1] 8.[2] Plaintiffs argue that the emphasized statement was misleading because it omitted that the SurgiBot's 501(k) application lacked the human-factors data needed for FDA approval.

Defendants argue that Rule 9(b) of the Federal Rules of Civil Procedure requires plaintiffs to plead their Section 11 claim with particularity. According to defendants, when, in support of their Section 11 claim, plaintiffs "make[] an allegation that has the substance of fraud," they must allege with particularity that the relevant statements were false, as required by Federal Rule of Civil Procedure 9(b). Cozzarelli, 549 F.3d at 629.

Unlike in Cozzarelli, the amended complaint does not treat the 2016 ATM Prospectus statements "as part of a single, coordinated scheme to defraud investors." Id. Instead, the amended

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[2] Although plaintiffs claim only that the statement in the 2016 ATM Prospectus was false without specifying additional false statements in the registration statement, defendants do not raise the issue. Thus, the court assumes that the 2016 ATM Prospectus was incorporated into the relevant registration statement, allowing for a Section 11 claim. See Cozzarelli, 549 F.3d at 629 n.4.

complaint segregates the 2016 ATM Prospectus statements from plaintiffs' allegations of fraud under Section 10(b) and Rule 10b-5. Moreover, the amended complaint expressly pleads ordinary negligence and strict liability in connection with the Section 11 claims. See Am. Compl. ¶¶ 105, 122(b), 126. Furthermore, the amended complaint "expressly disclaim[s] that the Securities Act Defendants acted with fraudulent intent or scienter." Id. ¶ 100. Thus, the court assumes without deciding that Rule 9(b) does not apply. See In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 270–73 (3d Cir. 2006).

Even without Rule 9(b), plaintiffs must "provide[] credible explanations of the falsity" of the 2016 ATM Prospectus's statements to "nudge[] the claims across the line form conceivable to plausible." Cozzarelli, 549 F.3d at 630 (alteration and quotation omitted). As they did with the statements underlying the Exchange Act claims, plaintiffs argue that the statement in the 2016 ATM Prospectus is misleading because it "omitted to inform investors that the FDA had already told Defendants that human factors data was essential to approval of the 510(k) application and, as a result, the 510(k) application as submitted was materially deficient." [D.E. 88] 30. As with the Exchange Act claims, however, the amended complaint's allegations neither mention this theory nor support it. At bottom, plaintiffs do not plausibly allege the omission of any material fact that made TransEnterix's stated anticipation of FDA approval and intention to thereafter commercialize SurgiBot misleading.

The same conclusion follows if the 2016 ATM Prospectus's statements express opinions. To hold an issuer liable for an opinion under Section 11's omissions clause,

> The investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.

Omnicare, Inc., 135 S. Ct. at 1332. "The core inquiry is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself." See Tongue, 816 F.3d at 210–14 (quoting Omnicare, 135 S. Ct. at 1329). In their amended complaint, plaintiffs do not plausibly allege the existence of a material fact going to the basis for TransEnterix's opinion the omission of which made the statement misleading.

B.

Section 11 also contains a standing requirement governing who can maintain a suit under Section 11. Section 11 states that "[i]n case any part of the registration statement . . . contained an untrue statement . . . any person acquiring such security . . . may . . . sue." 15 U.S.C. § 77k(a). Standing under Section 11 is limited to the "narrow class of persons consisting of those who purchase securities that are the direct subject of the prospectus and registration statement." Krim v. pcOrder.com, Inc., 402 F.3d 489, 495 (5th Cir. 2005) (quotations omitted).

The parties debate the specificity with which plaintiffs must allege that their shares are traceable to the 2016 at-the-market offering. Plaintiffs cite several district court cases holding that plaintiffs need only include the barebones allegation that they purchased stock pursuant to or traceable to the relevant offering. See [D.E. 88] 31–32. The First and Ninth Circuits have rejected this view. See In re Ariad Pharm., Inc. Sec. Litig., 842 F.3d 744, 755–56 (1st Cir. 2016); In re Century Aluminum Co. Sec. Litig., 729 F.3d 1104, 1107 (9th Cir. 2013). Relying on Iqbal and Twombly, these courts held that the complaint must set forth facts plausibly suggesting that plaintiffs' shares were issued as part of the relevant offering. In analyzing standing under Section 12(a)(2), the Fourth Circuit in Yates cited Century Aluminum and a First Circuit case to the same effect in holding that "using the 'pursuant and/or traceable to' language—coupled with sufficient

supporting facts—can give rise to a plausible inference of standing in certain circumstances." Yates, 744 F.3d at 900. The Fourth Circuit held that the plaintiffs had not plausibly alleged standing because the complaint lacked "supporting facts sufficient to push the claim into the realm of plausibility." Id. This court concludes that the Fourth Circuit would subject allegations of standing under Section 11 to the same plausibility analysis. Thus, the court evaluates plaintiffs' allegations concerning standing in light of Iqbal and Twombly.

The level of factual specificity required to adequately plead standing under Section 11 depends on the context. Where all of the company's shares were issued under a single registration statement, alleging simply that the plaintiffs' shares are traceable to the offering suffices. "No further factual enhancement is needed because by definition all of the company's shares will be directly traceable to the offering in question." In re Century Aluminum Co., 729 F.3d at 1107 (emphasis in original). But where the company has issued shares in multiple offerings under more than one registration statement, "a greater level of factual specificity will be needed before a court can reasonably infer that shares purchased in the aftermarket are traceable to a particular offering." Id. In that case, "the plaintiff must prove that his or her shares were issued under the allegedly false or misleading registration statement, rather than some other registration statement." In re Ariad Pharms., Inc., 842 F.3d at 755 (alteration and quotation omitted); see In re Century Aluminum Co., 729 F.3d at 1106.

Plaintiffs can satisfy this requirement in two ways. They "could prove that they purchased their shares directly in the secondary offering itself." In re Century Aluminum Co., 729 F.3d at 1106; see In re Ariad Pharms., Inc., 842 F.3d at 756. Or they "could prove that their shares, although purchased in the aftermarket, can be traced back to the secondary offering." In re Century Aluminum Co., 729 F.3d at 1106. Plaintiffs must "trace the chain of title for their shares back to the secondary

offering, starting with their own purchases and ending with someone who bought directly in the secondary offering." Id. at 1106–07.

Here, plaintiffs' allegations lack factual enhancement plausibly suggesting that their shares are traceable to the 2016 at-the-market offering. Plaintiffs do not allege that they purchased their shares directly in the 2016 at-the-market offering itself. Instead, plaintiffs allege only that they "purchased TransEnterix securities offered in the 'at-the-market' offering." Am. Compl. ¶ 131. Purchasing shares offered in the offering does not mean that plaintiffs purchased shares directly in the offering itself. They could just as well have purchased shares from someone else who had purchased shares directly in the offering. The shares plaintiffs purchased would still have been "offered in the in the at-the-market offering."

Plaintiffs must plead facts suggesting that the shares, although purchased in the aftermarket, can be traced back to the 2016 at-the-market offering. The 2016 at-the-market offering involved the sale of approximately 8.7 million shares. See Am. Compl. ¶¶ 31, 119. According to the 2016 ATM Prospectus, however, TransEnterix had issued over 100 million shares in multiple offerings by the time it commenced the 2016 at-the-market offering. See [D.E. 82-1] 11. That means, after the offering commenced, roughly 92% of the shares available for purchase by the public were not issued under the 2016 ATM Prospectus. "Accepting the allegations as true, plaintiffs' shares could have come from the secondary offering, but the obvious alternative explanation is that they could instead have come from the pool of previously issued shares." See In re Century Aluminum Co., 729 F.3d at 1108 (quotations omitted). Plaintiffs' conclusory allegations do not warrant a plausible inference that the shares are traceable to the 2016 at-the-market offering. See In re Ariad Pharms., Inc., 842 F.3d at 756; In re Century Aluminum Co., 729 F.3d at 1107–08; cf. Yates, 744 F.3d at 899–901.

Thus, plaintiffs have not adequately alleged that they have standing to maintain their Section 11 claim.

C.

Plaintiffs' Section 15 claims against individual TransEnterix directors and officers fail "because that section creates control-person liability only where Sections 11 or 12 have been violated." Cozzarelli, 549 F.3d at 630; see Yates, 744 F.3d at 901 n.14.

D.

The Securities Act, like the Securities Exchange Act, contains a safe-harbor provision. See 15 U.S.C. § 77z-2. The Securities Act and Exchange Act provisions are "identical in all significant respects," and courts employ the same analysis to both. In re Constellation Energy Grp., Inc. Sec. Litig., 738 F. Supp. 2d 614, 625 n.9 (D. Md. 2010). Like the identical statements analyzed above that underlie plaintiffs' Securities Exchange Act claims, the safe harbor protects the challenged statements in the 2016 ATM Prospectus because they are forward looking and plaintiffs have not adequately alleged that they were made with actual knowledge that they were false or misleading.

V.

Plaintiffs' response in opposition contains a footnote requesting leave to amend the complaint should the court find its allegations lacking. See [D.E. 88] 36 n.10. A party generally may amend its complaint once as a matter of course. Fed. R. Civ. P. 15(a)(1). Plaintiffs have done so. [D.E. 62]. Further amendments are allowed "only with the opposing party's written consent or the court's leave," although "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). Under Rule 7(b)(1) of the Federal Rules of Civil Procedure, "[a] request for a court order must be made by motion." A responsive brief is not an appropriate means to request leave to amend a complaint. See Jemsek v. N.C. Med. Bd., No. 5:16-CV-59-D, 2017 WL 696721, at *12 (E.D.N.C.

Feb. 21, 2017) (unpublished) (collecting cases). Moreover, Local Civil Rule 15.1(a) requires parties seeking leave to amend to attach a proposed amended complaint and a red-line version indicating how the proposed amended complaint differs from the complaint it amends. Thus, a court properly denies a plaintiff's request to amend the complaint "where, as here, the plaintiff fails to formally move to amend and fails to provide the district court with any proposed amended complaint or other indication of the amendments he wishes to make." Estrella v. Wells Fargo Bank, N.A., 497 F. App'x 361, 362 (4th Cir. 2012) (per curiam) (unpublished). The Fourth Circuit has applied this rationale in cases alleging violations of the federal securities statutes. See Cozzarelli, 549 F.3d at 630–31. Because plaintiffs did not file a motion to amend and a proposed amended complaint, the court denies their request for leave to amend. See Jemsek, 2017 WL 696721, at *12.

VI.

In sum, the court GRANTS defendants' motions to dismiss [D.E. 82, 84] and DISMISSES the amended complaint without prejudice. If plaintiffs wish to file a motion to amend, any such motion is due no later than October 6, 2017.

SO ORDERED. This 22 day of September 2017.

JAMES C. DEVER III
Chief United States District Judge